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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/755,544  | 01/12/2004  | Marc-Andre Poupart   | 13/121                       | 1310             |
| 28513   | 7590        | 07/12/2005           | EXAMINER                     |                  |
| MICHAEL P. MORRIS<br>BOEHRINGER INGELHEIM CORPORATION<br>900 RIDGEBURY RD<br>P O BOX 368<br>RIDGEFIELD, CT 06877-0368 |             |                      | PAVIGLIANITI, ANTHONY JOSEPH |                  |
|   |             |                      | ART UNIT                     | PAPER NUMBER     |
|   |             |                      | 1626                         |                  |
| DATE MAILED: 07/12/2005   |             |                      |                              |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/755,544

Applicant(s)

POUPART ET AL.

Examiner

Anthony J. Paviglianiti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 - 42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1 - 42 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

**Claims 1 – 42** are pending in the instant application.

**Priority**

The present application claims benefit of U.S. Provisional Application No. 60/441,674, filed January 22, 2003.

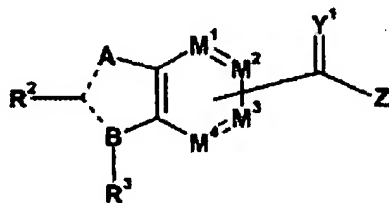
**Information Disclosure Statement**

The Information Disclosure Statement filed on September 2, 2004, is in compliance with 37 C.F.R. §1.97, and was considered by the examiner.

**Election/Restrictions**

The Markush groups set forth in the claims include both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. **For these reasons provided below, restriction to one of the following inventions is required under 35 U.S.C. 121**, wherein an Invention is a set of patentably distinct inventions of a broad statutory category (e.g., compounds, methods of use, methods of making, etc.):

- I. Claims 1 – 27 and 33 – 41**, drawn to compounds or compositions of Formula (I),

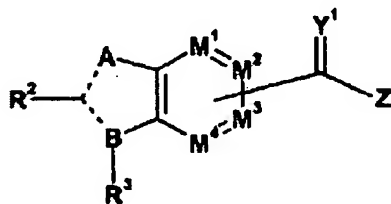


, or compounds or compositions of formula (I)

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combined with other agents such as antiviral agents, classified in class 546, subclass 277.4; class 548, subclasses 453, 494; and other classes and subclasses.

**II. Claims 28 – 32 and 42, drawn to methods of use of compounds or compositions**



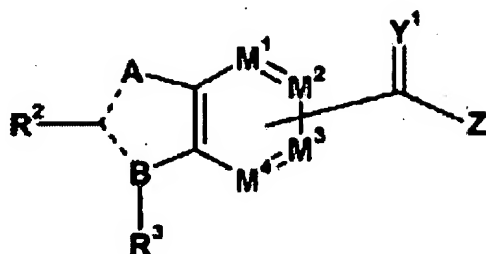
of formula (I), , classified in class 514, subclasses 338, 339, 415, and in other subclasses.

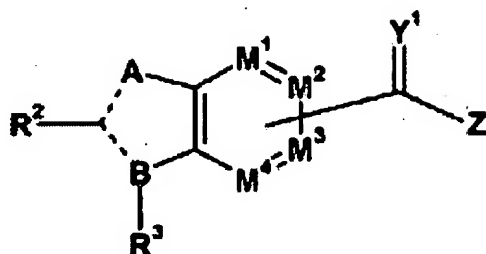
**In addition to an election of one of the above Groups, restriction is further required under 35 U.S.C. §121 as follows:**

In accordance with the decisions in In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980) and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App & Int. 1984), restriction of a Markush group is proper where the compounds with the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. §103 with respect to the other member(s).

**Whether Group I or Group II is elected, an election of a single compound is further required, including an exact definition of each substitution on the base molecule, formula (I), where a single member at each substituent group is selected. For example, as the base molecule**

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of formula (I), , has substituent group  $R^2$ , where  $R^2$  is recited to be “selected from the group consisting of: H, (C<sub>1-6</sub>)alkyl optionally substituted with halogen, OR<sup>11</sup>, SR<sup>11</sup> or N(R<sup>12</sup>)<sub>2</sub>, wherein  $R^{11}$  and  $R^{12}$  is independently H, (C<sub>1-6</sub>) alkyl, (C<sub>3-7</sub>) cycloalkyl, (C<sub>1-6</sub>)alkyl-(C<sub>3-7</sub>)cycloalkyl, (C<sub>1-6</sub>)alkyl-aryl or (C<sub>1-6</sub>) alkyl-Het, said aryl or Het optionally substituted by R<sup>160</sup>; or both  $R^{12}$  are covalently bonded together and to the nitrogen to which they are both attached to form a 5, 6, or 7-membered saturated heterocycle,” then applicant must select a single substituent representing  $R^2$ , such as a 2-pyridyl group (as in “Example 3” in the Specification at page 42, line 23), as well as specific representative values for each variable position (A, B, M<sup>1</sup>, M<sup>2</sup>, M<sup>3</sup>, M<sup>4</sup>, Y<sup>1</sup> and Z, etc.), including the point of attachment to the ring, if applicable, so that a single compound is identified, such as “1-cyclopentyl-3-methyl-2-(2-pyridyl)indole-5-carboxylic acid” (“Example 3” in the Specification).

One suggestion for the election of a single chemical compound would be to select one of the compounds disclosed as Examples 3 – 6 (Specification at pages 42 – 48) or Compounds # 101 – 129 (Specification at pages 51 – 54).

If **Group II** is elected, then **election of a specific method of use, along with an elected compound of formula (I), is required**; for example, a “method of treating HCV infection,” and the compound, “1-cyclopentyl-3-methyl-2-(2-pyridyl)indole-5-carboxylic acid” (Example 3).

In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected

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compound (compounds which are so similar as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim which fall into the same class and subclass as the elected compound, but may also include additional compounds which fall in related subclasses.

Examination will then proceed on the elected compound *and* the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits.

Note that the restriction requirement will not be made final until such time as Applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making the compounds under investigation. This will be set forth by reference to specific class(es) and subclass(es) examined.

Should Applicant traverse on the ground that the compounds are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

All compounds falling outside of the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to non-elected subject matter and will be withdrawn from consideration under 35 U.S.C. §121 and 37 C.F.R. §1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter.

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The provisions of 35 U.S.C. §121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(i).

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can set forth a group of compounds which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP §608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

***Rationale Establishing Patentable Distinctiveness Within Each Group***

Each Group listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP §806.04, MPEP §808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group); i.e., they are patentable over each other. Chemical structures which are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be

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overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lahu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

**The above Groups represent general areas wherein the inventions are independent and distinct, each from the other, because of the following reasons:**

**Group I and Group II** are related as product and method of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially-different process of using that product. MPEP §806.05(h). Applying this rule to the instant case, the process for using the products as claimed – for example, as a method for treating Hepatitis C Virus (HCV) infection – can be practiced with a materially different product than the compounds of formula (I), such as “interferon alfa.” See, e.g., Lauer, G., and Walker, B., “Hepatitis C Virus Infection,” N. Engl. J. Med., vol. 345(1), pages 41 – 52 (July 2001), at page 46, col. 1, lines 23 – 25. The inventions are therefore distinct and restriction is proper.

In addition, because of the plethora of classes and subclasses in each of the Groups, a serious burden is imposed upon the examiner to perform a complete search of the defined areas. Therefore, for the reasons given above, the restriction set forth is proper, and not to restrict would impose a serious burden in the examination of this application.



**Advisory of Rejoinder**

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

**During a telephone conversation with Philip Datlow, Esq., on June 29, 2005, the above restriction requirements were discussed, but applicant did not elect by telephone.**

Applicant is advised that the reply to this requirement to be complete must include an election of the Invention to be examined even though the requirement be traversed. 37 C.F.R. §1.143.


Applicant is further advised that a reply to this requirement must identify the specific compound that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

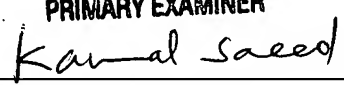
**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Anthony J. Paviglianiti** whose telephone number is **(571) 272-3107**. The examiner can normally be reached on Monday-Friday, 8:30 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, may be reached at (571) 272-0699. **The FAX phone number for the organization where this application or proceeding is assigned is (571) 273-8300.** Please note that this is a new central FAX number for all official correspondence.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
\_\_\_\_\_  
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TC-1600, Art Unit 1626

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